REMARKS

This amendment serves as the submission accompanying the applicants' Request for Continued Examination (RCE) filed pursuant to 37 C.F.R. § 1.114.

Claims 154-172 and 241-253 were pending. Claim 245 is being canceled. Claim 154 is being amended to clarify the constituents of the composition applied to the biological tissue. Claim 162 is being amended to correct the dependency. Support for the amendments to claim 162 can be found, for example, on page 126, under the Sub-header "Tumor excision site" in the specification as originally filed. Claims 254-255 are new. Support for new claims 254-255 can be found, for example, in original claim 197 and lines 1-5 on page 5 of the specification as originally filed. No new matter is being introduced. Upon entry of these amendments, claims 154-172, 241-244, and 246-255 will be pending.

As an initial matter, Applicants thank the Examiner for his time and courtesy in conducting an Examiner interview on May 29, 2008. During the interview, Applicants' proposed amendments were discussed with the Examiner (discussed in more detail below). Applicants acknowledge that the personal interview was helpful in enabling Applicants to understand the Examiner's position and to focus the arguments that follow.

Claim Rejections Under 35 U.S.C. §102

Claims 154-157, 161, 165-166, 168, 172 and 241-246 are rejected as being anticipated by U.S. Published Application No. 2001/0055615 to Wallace (hereafter "Wallace").

The above rejections are set forth in the Office Action at pages 2-4 and are not repeated herein for purpose of brevity. Rather, Applicants wish to focus on the Examiner's "Response to Arguments" beginning on page 4 and ending with the first paragraph of page 5 of the Office Action dated December 20, 2007. In particular, Applicants will address the Examiner's comments with regard to Wallace's disclosure: "Although, the two-component polymer compositions that, when mixed together, rapidly react to form a matrix at the site of administration, there will be always a portion of the non-reacted polymers. The non-reactive remainder of the compound is considered to be its 'core' and effective for reacting with the

biological tissue to form covalent bonds between the synthetic polymer and the tissue…" In brief, although the Examiner recognizes that Wallace is directed to a two-component gelling system, the Examiner is of the opinion that some portion of one component of the polymer composition of Wallace can be non-reacted with the other component, but instead reacts with the biological tissue.

Wallace's two-component crosslinking system is expressly distinguished in the Background of the Invention of the subject application.[1] Unlike Wallace, the claimed invention is directed to a method of affecting biological processes by applying a composition having a synthetic polymer and a drug; the synthetic polymer is not in admixture with another polymer that is reactive with the synthetic polymer. In other words, the claimed invention is directed to a single synthetic polymer which forms covalent bonds with biological tissue, not a two-component crosslinking system with a possible residual non-crosslinked component.

During the Examiner's interview, the Examiner considered Applicants' proposed amendment to replace "comprising" with "consisting essentially of" in reciting the constituent of the composition to be applied to the biological tissue, thus limiting the composition to a single synthetic polymer (and a drug). The Examiner was receptive to such amendments. In addition, it was discussed that the claimed invention pertains to a single synthetic polymer that is not combined with a second polymer either before or after application to the tissue.

Consistent with the discussion with the Examiner, claim 154 is being amended to specify that, in the step of applying a composition to the biological tissue, the composition consists essentially of a synthetic polymer and a drug, and wherein the synthetic polymer is not in admixture with any other synthetic polymer that is reactive with the synthetic polymer prior to applying the composition to the tissue or following applying the composition to the biological tissue, thus excluding the possibility of the synthetic polymer being mixed (or reacting) with another synthetic polymer at any time. Applicants respectfully submit that amended claim 154 and its dependent claims are novel in view of Wallace.

[1] U.S. Patent No. 6, 312,725, which is the issued patent of Wallace, is discussed under the sub-header "Description of the Related Art" in the subject application.

Claims 154, 155, 161, 169-172 and 241-246 are rejected as being anticipated by U.S. Patent No. 6,166,130 to Rhee (hereafter "Rhee").

For the same rationale as set forth above, amended claim 154 is not anticipated by Rhee. Rhee does not disclose a method of affecting biological processes by applying a composition to biological tissue, wherein the composition consists essentially of a synthetic polymer and a drug, and wherein the synthetic polymer is not in admixture with any other synthetic polymer that is reactive with the synthetic polymer prior to applying the composition to the tissue or following applying the composition to the biological tissue. Instead, Rhee is directed to a two-component gelling system in which two synthetic polymers crosslink with each other. Accordingly, amended claim 154 and its dependent claims are novel in view of Rhee.

Claims 154, 155 and 158 are rejected as being anticipated by U.S. Patent No. 6,280,727 to Prior (hereafter "Prior").

Applicants wish to focus on the Examiner's "Response to Arguments" on page 8 of the Office Action. In particular, Applicants will address the Examiner's characterization of Prior's disclosure with regard to a hemostatic composition. The Examiner is of the opinion that Prior discloses a composition comprising thrombin and polyethylene glycol, and "the incorporation of thrombin into polyethylene glycol polymer is equivalent to multiple activated groups and provides a composition for use in the field of tissue treatment and repair."

Applicants respectfully disagree with the Examiner's characterization of Prior's disclosure. In Prior, polyethylene glycol (PEG) was mixed in the hemostatic composition to stabilize thrombin. Thrombin is a separate component of the composition. Thrombin is not a functional group of PEG and cannot be equated to the functional group Y of the claimed synthetic polymer (*e.g.*, amino- or thiol-reactive groups) that form covalent bonds with the tissue. In fact, Prior does not disclose any component of the hemostatic composition that is capable of forming covalent bonds with the tissue. Accordingly, Prior does not anticipate amended claim 154 or its dependent claims.

Claim rejections under 35 U.S.C. §103

Claims 154, 162-164, 167 and 247-249 are rejected as unpatentable over Wallace or Rhee, in view of U.S. Patent No. 5,716,404 to Vacanti (hereafter "Vacanti").

The cited references do not teach or suggest the claimed features of claim 154, as amended. Amended claim 154 is directed to affecting biological processes by applying to biological tissue a composition having a single synthetic polymer and a drug, whereby the functional groups Y of the single synthetic polymer form covalent bonds with the functional groups X of the tissue. The claimed feature is further clarified in amended claim 154, which recites that the composition consists essentially of a synthetic polymer and a drug, and wherein the synthetic polymer is not in admixture with any other synthetic polymer that is reactive with the synthetic polymer prior to applying the composition to the tissue or following applying the composition to the biological tissue.

Neither Wallace nor Rhee teaches or suggests forming covalent bonds between a single synthetic polymer having multiple activated groups and tissue in which the multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue. Instead, both are directed to two-component systems in which the two components react with each other. This scenario is expressly excluded in amended claim 154.

The deficiency of Wallace or Rhee is not cured by reliance on a secondary reference that does not disclose or suggest the missing elements. The Examiner points out that Vacanti is relied upon to show "reconstruction or augmentation of breast tissue." There are any number of references that can be cited that disclose "reconstruction or augmentation of breast tissue." However, the claimed element (*i.e.*, a composition consisting essentially of a synthetic polymer and a drug) that is missing in Wallace or Rhee is also lacking in Vacanti. Accordingly, Applicants submit that a prima facie case of obviousness has not been established as to the subject matter of claim 154, as amended.

Further, there is additional evidence that Vacanti is deficient as a secondary reference. Vacanti does not teach or suggest the features of claims 247-249. Claims 247-249 specify that the drug is a cell cycle inhibitor (*e.g.*, paclitaxel), which inhibits cell proliferation. This feature could not have been taught or suggested in Vacanti. In fact, Vacanti teaches

away from using cell cycle inhibitors because the polymeric matrix in Vacanti serves to promote cell proliferation and tissue regrowth.

Accordingly, Wallace or Rhee, alone or in combination with Vacanti, do not render claims 154, 162-164, 167 and 247-255 obvious.

Claims 154, 167 and 247-249 are rejected as unpatentable over Wallace, Rhee, or Wadstrom in view of U.S. Patent No. 5,922,676 to Pasqualini (hereafter "Pasqualini") and U.S. Published Application No. 2002/0055666 to Hunter (hereafter "Hunter").

The cited references do not teach or suggest the claimed features of claim 154, as amended. As discussed above, neither Wallace nor Rhee teaches or suggests forming covalent bonds between a single synthetic polymer having multiple activated groups and tissue in which the multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue. Instead, both are directed to two-component systems in which the two components react with each other. This scenario is expressly excluded in amended claim 154.

The deficiency of Wallace or Rhee is not cured by reliance on Pasqualini, which does not disclose the missing elements. Pasqualini is limited to methods of inhibiting angiogenesis and cytokine-mediated endothelial cell growth and migration using superfibronectin, *i.e.*, adhesive multiple fibronectin molecules. Pasqualini does not teach or suggest that superfibronectin has multiple activated groups that can form covalent bonds with tissue. In addition, Pasqualini does not teach or suggest the features of claim 167. Claim 167 is directed to a method of affecting (*e.g.*, mitigating or preventing) adhesion formation caused by colon tumor resection surgery. Pasqualini's disclosure is limited to inhibiting tumor growth, not adhesion formation due to surgery. Accordingly, Wallace or Rhee, alone or in combination with Pasqualini, do not render claims 154, 162-164, 167 and 247-255 obvious.

Similarly, Hunter also does not disclose the claimed elements that are missing in Wallace or Rhee. Hunter describes combining radioactive therapy and cell-cycle inhibitors for treating diseases. Hunter does not teach or suggest forming covalent bonds between a single synthetic polymer having multiple activated groups and tissue in which the

multiple activated groups (Y) of the synthetic polymer react with functional groups X of the tissue.

Accordingly, Wallace or Rhee, alone or in combination with Hunter, do not render claims 154, 162-164, 167 and 247-255 obvious.

Conclusion

In view of the above amendments and discussion, amended claim 154 and its dependent claims are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
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